

**SUMMARY OF  
U.S. NUCLEAR REGULATORY COMMISSION/U.S. DEPARTMENT OF ENERGY  
QUARTERLY QUALITY ASSURANCE MEETING  
January 22, 2003**

**Introduction:**

The U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Energy (DOE) held a public Quarterly Quality Assurance (QA) Meeting regarding the Yucca Mountain Project (YMP) on January 22, 2003. The meeting was held at the NRC office in Rockville, Maryland, and via video conference to the DOE office in Las Vegas, Nevada, and the Center for Nuclear Waste Regulatory Analyses in San Antonio, Texas. Participants included representatives from the NRC, DOE, Bechtel SAIC Co. LLC (BSC), the State of Nevada, and Clark County. Copies of the agenda and a list of attendees are attached as Enclosures 1 and 2, respectively.

Joseph Ziegler (DOE) convened the QA meeting with opening remarks. Mr. Ziegler re-introduced Denny Brown as the new Director of Office of Quality Assurance.

Mr. Brown stated that he will include the Policy Statement developed by Dr. Margaret Chu (DOE) in Revision 13 of the Quality Assurance Requirement Description (QARD). Also, DOE management has a renewed emphasis on QA and realizes that a high level of quality in the aspects of DOE's efforts, including data and software, is needed for a potential license application. Mr. Brown said that DOE is striving to simplify their QA procedures and processes. Mr. Brown emphasized that DOE and BSC management and staff must be held accountable to implement the QA program by following established procedures.

Thomas Matula (NRC) asked Mr. Brown how DOE will hold BSC accountable for quality-affecting activities that they perform. Mr. Brown replied by saying BSC will be held accountable through performance measures and fees associated with the contract.

Attached to this summary are the Agenda, Attendance List, Presentations, and Action Items.

**Presentations:**

Mr. Brown presented the DOE Office of Civilian Radioactive Waste Management (OCRWM) QA Approach. Mr. Brown presented introductory information regarding Dr. Chu's renewed emphasis on increased quality, the importance of quality in developing the License Application (LA), and the necessity for individual, management, and senior management accountability regarding procedure implementation. Mr. Brown then discussed DOE OCRWM's path forward which includes simplifying processes and procedures, holding process and procedure implementers accountable, using benchmarking as a method to improve performance, establishing additional DOE Quality Engineering functions, increasing DOE's QA staff involvement in processes, and concentrating on areas of focus for LA. Mr. Brown also discussed the areas of major focus for LA including confirming software qualification, verifying model validation integrity, and assuring data quality. Mr. Brown concluded by stating that QA is critical to LA, and every individual is accountable for implementation of procedures.

Mr. Brown presented the organizational structure and current levels of staffing for OCRWM, Navarro Quality Services, and BSC QA organizations. Larry Campbell (NRC) asked if DOE Office of Environmental Management (EM-5) has stopped performing audits for DOE. Mr.

Brown stated that DOE OQA will now perform audits previously performed by EM-5. Mr. Matula asked what the reporting relationship is between OQA and Navarro Quality Services. Mr. Brown stated that OQA assigns tasks to Navarro and Navarro reports directly to OQA. Don Krisha (BSC) presented the BSC QA organizational structure and stated that there are currently 67 people which will increase to approximately 80 people.

Mr. Krisha presented DOE and BSC's noteworthy practices which include developing specific roles, responsibilities, authority, and accountability for BSC QA organization, completing the performance-based software surveillance as part of CAR-BSC-01-C-002 regarding software issues, increasing management attention and improving information exchange between the DOE line organizations and OQA. Additional noteworthy practices that were discussed involved developing an annual refresher QA orientation computer-based training used to update current employee's training and improve current new hire indoctrination, and improved the self-assessment process by developing a handbook to assist personnel in performing self-assessments. Mr. Matula asked how BSC will hold its staff accountable for implementing the QA program and how are self-assessments performed. Mr. Krisha said that each employee has accountability measures as a part of their performance evaluation package, and that self-assessments are scheduled to be performed on processes using specified guidance. Robert Latta (NRC) asked how self assessments are measured and how effective the self assessments are in identifying problems. Mr. Krisha said that the BSC Quality Systems Organization reviews the self assessment reports to determine if they are completed properly. Nancy Williams (BSC) stated that BSC measures the number of deficiencies which are self identified.

Mr. Brown presented the status of the QARD. The QARD will be reviewed and revised as necessary to ensure that applicable requirements are identified, documented, and traceable to regulatory requirements. Revision 13 to the QARD, currently in the review process, addresses comments from an independent review of the QARD and the OCRWM re-organization. Revision 14 to the QARD will be a more comprehensive revision and will include 10 CFR Part 63 requirements. Mr. Brown stated that draft versions of Revisions 13 and 14 of the QARD will be shared with the NRC before being issued in final form and that a public meeting may be needed to discuss Revision 14. Mr. Ziegler asked if the NRC could provide examples or references of good QA programs which separate regulatory requirements. Mr. Campbell said that NRC can provide several references for DOE to consider.

Mr. Latta asked if the independent review of the QARD was related to the statement in the Management Improvement Initiatives (MII) indicating that the QARD was confusing and difficult to implement. Mr. Brown said that the initial assumption that the QARD was confusing and difficult to implement was not supported by the independent review of the QARD. The changes that resulted from the independent review were relatively minor. Mr. Brown also stated that the project would be issuing a letter report documenting the results of the independent review of the QARD.

Mr. Brown presented information regarding the ongoing procedure transition efforts. DOE and BSC will have separate and discrete procedure sets to control their respective activities, as appropriate. Mr. Brown described the procedure transition goals for DOE, the transition process, the procedure hierarchy, processing of procedures, and transition priorities. Mr. Brown also stated that BSC has defined a new procedure hierarchy that correlates to their organizational structure.

Mr. Latta stated that the MII concluded that procedures were ineffective and he asked if the procedures scheduled for revision had been formally evaluated to determine the necessary changes. Mr. Brown stated that he was not aware that the MII drew this conclusion and would research it. Mr. Matula followed up by asking how DOE controls the procedure review process. Mr. Brown noted that DOE controls the procedure review process through surveillances, audits, and self assessments. James King (BSC) added that the first steps in revising procedures was to assign ownership for each procedure, have the owners review them, and then make recommendations for changes. This is an ongoing process. Relative to this issue, Mr. Latta questioned the status of a recent Audit Observation Inquiry concerning the performance of procedural reviews by OQA to ensure compliance with the requirements of the QARD. Mr. Brown indicated that he was unaware of the status of this issue but that he would look into the matter.

Mr. Brown and Jean Younker (BSC) presented information regarding data management. Mr. Brown stated that 1,475 data sets are needed for LA products of which 900 are qualified, 425 require verification, and 150 require qualification. Ms. Younker provided information regarding open Deficiency Reports (DRs) and stated that BSC will perform surveillances and audits of data management in FY03. OQA plans to perform an in-depth performance-based audit of data management processes in FY03.

Mr. Latta asked Mr. Brown to describe the procedure revision process related to the recent review of Procedure AP-SIII.2Q, Rev.1, ICN 0, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data." He also asked why this quality-affecting activity (1) failed to identify a potential area of noncompliance with the requirements of the QARD related to the use of unqualified data, and (2) why this item of potential non-compliance has remained unanswered for over three months. Mr. Brown replied that Revision 13 of the QARD will address part of the issue. Mr. Brown also state that Procedure AP-SIII.2Q will be thoroughly reviewed during the upcoming audit to make sure that unqualified data, characterized as "Not Established Fact," complies with the requirements in Supplement III of the QARD.

Mr. Robert Keele (BSC) presented information regarding Software QA. Mr. Keele stated that more than 600 computer codes have been qualified and base-lined for use in scientific and engineering studies over the last five years. Mr. Keele also stated that experience in the development of major technical products and the findings of QA oversight activities mandate improvement in the process to develop, qualify, and manage software to meet expectations for LA. BSC is submitting codes used in LA work to a new Independent Verification and Validation (IV&V) process. Mr. Latta inquired about legacy codes (developed prior to May 17, 2002) verification and the results of a recent software surveillance which concluded that the current IV&V process is not effective in ensuring the repeatability of software. Mr. Keele stated that legacy codes used in License Application supporting technical products will be re-tested using the newly developed IV&V process. Mr. Latta asked if the new process was in place and if the legacy codes would be re-tested prior to use. Mr. Keele indicated that the new procedure governing the IV&V function for quality-affecting legacy software was under development and that there was no plan to submit the legacy codes to IV&V prior to use. Mr. Keele went on to say that Corrective Action Report (CAR) BSC-01-C-002 identifies a number of instances of noncompliance with procedure requirements involving code development and that the CAR response contains 25 root-cause-related actions, which have been included as MII actions. Nine corrective actions are completed and verified, four are completed and verification is requested, and 12 remain to be completed. Mr. Matula asked when the remaining 12 corrective

actions will be completed. Mr. Keele stated that they will be completed by April 14, 2004. Also, OQA will perform a performance-based audit of software QA in the spring of 2003.

Mr. Keele also presented information regarding the IV&V Review team, "Software Experts (QA-0204-01)." A copy of the information discussed is included in the attached presentation material.

Mr. Krisha presented information regarding QA for models. Mr. Krisha stated that more than 80 models were developed, documented, and used on the project prior to the formal initiation of license application activities. OQA and BSC QA have planned additional performance-based audits which will include evaluation of the effectiveness of the new processes for model development, validation, and use.

Mr. Krisha presented information regarding Records Management and described the status of the three open DRs dealing with records management. Mr. Matula inquired about the status of degraded electronic records identified in CAR BSC-02-C-129 and if any of the records were lost. James Clark (BSC) stated that they will complete the data migration process by September 1, 2003. Priority will be given to quality-related data and will be completed by spring 2003. At that time, BSC will know what records are missing. Mr. Matula requested a summary and time line of the corrective action process for this matter. Mr. Brown agreed to provide the information by the next quarterly QA meeting.

Mr. Brown presented information regarding the Corrective Action Program. This is identified in the MII as an action to develop a single Corrective Action Program. Mr. Matula asked if Technical Evaluation Reports (TERs) and Deficiency Identification and Referrals (DIRs) are included in DOE's trend reports. Mr. Brown stated that they have been added and will be reflected in the next trend report. Mr. Latta asked if the single Corrective Action Program would incorporate other existing issue identification programs (i.e., TERs, DIRs). Russ Fray (BSC) stated that as currently envisioned the single Corrective Action Program would include the existing issue identification systems currently in the Condition and Issue Identification and Resolution System.

Mr. Krisha presented information regarding training. Mr. Krisha stated that new personnel are trained within 30 days of starting on the job, annual refresher training is performed, and Initial Prior (IP) training takes place before any quality-affecting work is started. Mr. Latta asked what is being done to address lingering training and qualification issues related to CAR BSC-02-C-01, which is over 400 days old. Mr. Krisha stated that each manager is responsible for assuring that their staff is trained before they are assigned work and that BSC is pursuing the resolution on CAR-BSC-02-C-01, and the associated DRs. Mr. Brown indicated that DOE management was currently reviewing this issue.

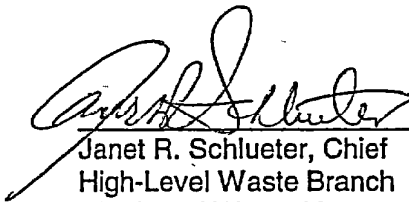
Mr. Ziegler (DOE) presented information regarding DOE's position on use of non-qualified data for closure of some Key Technical Issue (KTI) agreements. Janet Schlueter (NRC) stated that the DOE white paper dated December 24, 2002, is not clear in some areas. Specifically, the paper states "If any of the pre-LA results cannot be determined to be consistent with analyses conducted under full QA controls for the LA, a revised approach to resolution will be developed for each impacted KTI agreement item." Mr. Ziegler responded by saying that DOE does not expect that this will happen, but that there is a possibility that results may change based on analysis performed with fully qualified information. Mr. Ziegler stated that the sensitivity

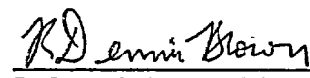
analysis performed using a partially qualified Total System Performance Analysis (TSPA) model to determine Bin 3 models (i.e., models where DOE will provide risk information as an alternative basis for closure of the KTI agreement) would be confirmed later with the fully-qualified TSPA used for LA. Mr. Matula emphasized that the regulations state that only qualified data will be used for important-to-safety items for LA. Mr. Matula verified that OQA was involved in the development of the DOE position and that the position meets the QARD requirements for use of qualified data for LA. Ms. Schlueter then stated that NRC will review DOE's position further and respond with the results of the review.

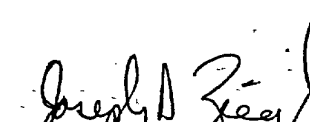
**Closing Remarks:**

Ms. Schlueter provided closing remarks which included an acknowledgment of the efforts of all meeting participants and Mr. Brown in working toward improving the QA program. Ms. Schlueter stated that NRC is concerned with the time it takes DOE to close CARs and the lack of success in implementing effective corrective action to preclude problem recurrence. Ms. Schlueter encouraged DOE to develop enhanced performance indicators and outcome metrics regarding MII key elements.

Mr. Brown stated that the meeting was productive and that he wishes to continue the working-level QA meetings to address and resolve issues.

 1/28/03 Date  
Janet R. Schlueter, Chief  
High-Level Waste Branch  
Division of Waste Management  
Office of Nuclear Material  
Safety and Safeguards  
U.S. Nuclear Regulatory Commission

 1/24/03 Date  
R. Dennis Brown, Director  
Office of Quality Assurance  
Office of Civilian Radioactive  
Waste Management  
U.S. Department of Energy

 1/28/03 Date  
Joseph D. Ziegler, Acting Director  
Office of License Application  
and Strategy  
Office of Repository Development  
U.S. Department of Energy